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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference PCA/KDH/KJ	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/KR2003/000704	International filing date (day/month/year) 08 APRIL 2003 (08.04.2003)	Priority date (day/month/year) 08 APRIL 2002 (08.04.2002)
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 35/78		
Applicant KIM, Dong-Hyun et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 07 NOVEMBER 2003 (07.11.2003)	Date of completion of this report 02 AUGUST 2004 (02.08.2004)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer YEO, Ho Sup Telephone No. 82-42-481-5627 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2003/000704

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement) under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language _____ which is
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed," and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☒ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☒ not complied with for the following reasons:

The present invention relates to a composition comprising a processed ginseng extract for the prevention or treatment of brain stroke and brain diseases.

- 1) Claims 1-10 are directed to a pharmaceutical composition.
2) Claims 11-12 are directed to a health care food.

Although the abovementioned groups of claims are relevant to the composition comprising the same active ingredient, there is no technical relationship among a pharmaceutical composition and health care food.

Hence, the application does not meet the requirement for unity of invention of Articles 3(4)(iii), 34(3) and Rule 13.1 PCT.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
☐ the parts relating to claims Nos.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims	1-12	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The present invention relates to a composition for treating or preventing brain stroke and brain diseases, comprising the extract of processed ginseng treated with acid followed by bio-converting treatment with lactic acid bacteria or intestinal bacteria as an active ingredient.

The following document has been considered for the purpose of this report :

D1 = Planta Med. 62(5), 453-7 (1996)

D1 discloses the production of saponin metabolites such as a compound K from ginseng saponins by human intestinal bacteria.

Even though D1 is relevant to the present invention, it does not describe the use of processed ginseng extract for the treatment or prevention of brain stroke and brain diseases.

Besides, the applicants have supplied data showing an improved pharmacological effect of the processed ginseng extract of the present invention, compared with the non-processed ginseng extract.

As a consequence, claims 1-12 meet the criteria set out in PCT Article 33(2)-(4).

INTERNATIOAL PRELIMINARY EXAMINATION REPORT

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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

- 1) Claim 11 is not based on the disclosure of the description. The expression "cancer and allergic diseases" should be replaced by "brain stroke and brain diseases".
- 2) The applicants have not supplied data showing that ginsenoside Rb1, Rb2, Rc, Rd, Re, Rf, Rg1 and 20-ginsenoside Rg3 of the present invention are useful for treating or preventing brain strokes and brain diseases. Therefore, the subject-matter of claim 8 is not fairly based on the disclosure of the description including the examples.